TAB J

65 FR 18434-01, 2000 WL 364076 (F.R.)

(Cite as: 65 FR 18434)

RULES and REGULATIONS

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Parts 409, 410, 411, 412, 413, 419, 424, 489, 498, and 1003

[HCFA-1005-FC]

RIN 0938-AI56

Office of Inspector General; Medicare Program; Prospective Payment System for Hospital Outpatient Services

Friday, April 7, 2000

*** The requested pages begin below ***

the portion of the applicable fee schedule amount determined to be associated with the item. The objective of this section is to prevent the hospital outpatient PPS from creating disincentives for the diffusion of valuable new technology by initially paying a rate significantly below the costs of these items. We believe that the "not insignificant" criterion was included in recognition that: (1) The costs of some new technologies would not be large enough relative to the fee schedule amount to provide disincentives for their use in the short run; and (2) that an excessive number of pass-through items could place a substantial burden on the claims processing systems of both HCFA and individual hospitals in a way that could hamper the rapid processing of pass-through payments for those items that would be significantly more costly than the applicable fee schedule amount. Therefore, in order to be consistent with the objectives of this section, we are establishing the following criteria for determining whether the costs of drugs, biologicals, and devices are "not insignificant" relative to the hospital outpatient department fee schedule amount:

(1) Its expected reasonable cost exceeds 25 percent of the applicable fee schedule amount for the associated service. ***18481**

(2) The expected reasonable cost of the new drug, biological, or device must exceed the portion of the fee schedule amount determined to be associated with the

drug, biological, or device by 25 percent.

(3) The difference between the expected, reasonable cost of the item and the portion of the hospital outpatient department fee schedule amount determined to be associated with the item exceed 10 percent of the applicable hospital outpatient department fee schedule amount.

The following illustrates the application of these three criteria.

Example: Let us assume that the reasonable cost of the new device ZZ is $32.00. ZZ is associated with HCPCS code 00000 assigned to APC 0001. The fee schedule amount for APC 0001 is $100.00. The portion of the fee schedule amount included in APC 0001 that represents the cost associated with the former device is $25.00.

1. (a) Multiply the fee schedule amount for APC 0001 by 25 percent

$100.00 x .25 = $25.00

(b) Compare the reasonable cost for ZZ to the product derived in Step 1

$32.00 > $25.00

Finding: The first criterion is met.

2. (a) Multiply the portion of the fee schedule amount for APC 0001 that is associated with a device by 25 percent

$25.00 x .25 = $6.25

(b) Subtract the portion of the fee schedule amount for APC 0001 attributable to a device from the reasonable cost for ZZ

$32.00 - $25.00 = $7.00

(c) Compare the remainder in Step 4 to the product in Step 2(a)

$7.00 > $6.25

Finding: The second criterion is met.

3. (a) Multiply the fee schedule amount for APC 0001 by 10 percent

$100.00 x .10 = $10.00

(b) Compare the remainder in Step 3 to the product derived in Step 3(a)

$7.00 @ $10.00

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Finding: The third criterion is not met. Therefore, new device ZZ is not eligible for transitional pass-through payment.

5. Calculating the Additional Payment

Section 1833(t)(6)(C)(i) of the Act requires that for drugs, biologicals, and radiopharmaceuticals, the additional payment be determined as the difference between the amount determined under section 1842(o) of the Act (95 percent of AWP) and the portion of the hospital outpatient department fee schedule amount determined by the Secretary to be associated with those items. For devices, the additional payment is the difference between the hospital's charges adjusted to costs and the portion of the applicable hospital outpatient department fee schedule amount associated with the device. Under section 1833(t)(7) of the Act, as added by section 201(i) of the BBRA 1999, the coinsurance amounts for beneficiaries are not affected by pass-through payments.

We will determine, on an item-by-item basis, the amount of the applicable fee schedule amount associated with the relevant drug, biological, or device. To the extent possible, hospital outpatient department claims data will be used to make these estimates. When necessary, external data pertaining to the costs of the drugs, biologicals and devices already included in the fee schedule amounts will be used to make these determinations.

Before January 1, 2002, charges for devices eligible for pass-throughs will be adjusted to cost on each claim by applying the individual hospital's average cost-to-charge ratio across all outpatient departments. The 1996 data do not allow for determination of which revenue center-specific ratios might be used for this purpose. We will examine claims for the latter half of 2000 and for 2001 in order to determine if a revenue center-specific set of cost-to-charge ratios should be used for 2002 and beyond.

A one-time exception to the general methodology described above pertains to current drugs and biologicals that will be eligible for transitional pass-throughs when the PPS is implemented. For this final rule, we revised many APC groups by removing, to the extent possible, many of these drugs and radiopharmaceuticals. Therefore, the payment rates for the APC groups with which these drugs are associated exclude the costs of these drugs and the total amount paid to hospitals for the drugs will be 95 percent of the applicable AWP. In order to be able to determine a coinsurance amount for these drugs, we needed to estimate what portion of this payment would have been included as part of the APC payment amount associated with these drugs and what portion would be the pass-through amount. Using an external survey of hospitals' drug acquisition costs, we determined the APC payment amount for many of these drugs as their average acquisition cost adjusted to year 2000 dollars. Where valid cost data were not available for individual drugs, we applied the following average ratios of acquisition cost to AWP calculated from the survey to determine the fee schedule amount: .68 for drugs with one manufacturer, .61 for multi-source drugs, and .43 multi-source drugs with generic competitors. In either case, the coinsurance amounts were determined as

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20 percent of these fee schedule amounts. It is important to note that these estimates do not affect the total payment to hospitals for these drugs (95 percent of AWP).

Because claims data are not available for most items that will be eligible for transitional pass-through payments for 2000 and 2001, it is extremely difficult to project expenditures under this provision. For this reason, and because many eligible items will be added after the system's implementation, we cannot estimate if, and to what extent, these payments would exceed 2.5 percent of total payments in 2000 and 2001. Therefore, there will be no uniform reduction factor applied to these payments during this period.

6. Process To Identify Items and To Obtain Codes for Items Subject to Transitional Pass-Throughs

We have identified a large number of items subject to the transitional pass-through payment through our own data-gathering activities or through comments on the proposed rule. Many of them already have HCPCS codes, and we are taking steps to establish temporary codes for the remaining items. We will make additional payments for these items when the hospital outpatient PPS system is implemented on July 1. A list of the items already known to us is set forth in Addendum K.

Other items potentially eligible for additional pass-through payments may not be known to us at this time. Because of systems limitations, if we do not know about an item, we will not be able to make additional payments for those items beginning on July 1, 2000. However, we will update our outpatient PPS on a quarterly basis beginning October 1, 2000 to add other items that are eligible for pass-through payments. Therefore, implementation of additional payment for any such item must wait until a later release of systems instructions, that is, in October 2000, January 2001 (annual update), or later.

A manufacturer or other interested party who wishes to bring items that may be eligible for additional transitional pass-through payments to our attention should mail requests for consideration of items to the following address ONLY: PPS New Tech/Pass-Throughs, Division of Practitioner and Ambulatory Care, Mailstop C4-03-06, Health Care Financing Administration, ***18482** 7500 Security Boulevard, Baltimore, MD 21244-1850.

To be considered, requests MUST include the following information:

- Trade/brand name of item.

- A detailed description of the clinical application of the item, including HCPCS code(s) to identify the procedure(s) with which the item is used. If the item replaces or improves upon an existing item, identify the predecessor item by trade/brand name and HCPCS code.

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- Current cost of the item to hospitals (i.e., actual cost paid by hospitals net of all discounts, rebates, and incentives in cash or in-kind). In other words, submit the best and latest information available that provides evidence of the hospital's actual cost for a specific item.

- Date of sale of first unit.

- For drugs, submit the most recent average wholesale price (AWP) of the drug and the date associated with the AWP quote.

- If the item requires FDA approval/clearance, submit information that confirms receipt of FDA approval/clearance and the date obtained.

- If the item already has an assigned HCPCS code, include the code and its descriptor in your submission plus a dated copy of the HCPCS code